

# Exhibit 1

to

Memorandum of United States in Opposition  
To Dey Defendants' Motion in Limine  
To Exclude Opinions of Mark Duggan, Ph.D

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL	)	
INDUSTRY AVERAGE WHOLESALE	)	
PRICE LITIGATION	)	MDL No. 1456
_____	)	Master Case No. 01-12257-PBS
	)	
THIS DOCUMENT RELATES TO:	)	Subcategory Case No. 06-11337-PBS
	)	
<i>United States of America ex rel. Ven-a-</i>	)	
<i>Care of the Florida Keys, Inc., et al. v.</i>	)	
<i>Dey, Inc., et al., Civil Action No. 05-</i>	)	
11084-PBS	)	

**DECLARATION OF MARK G. DUGGAN, Ph.D**  
**IN SUPPORT OF MOTION TO EXCLUDE**  
**CERTAIN TESTIMONY OF W. DAVID BRADFORD, Ph.D**

I, Mark G. Duggan, hereby declare as follows:

1. I am a Professor in the Department of Economics at the University of Maryland, College Park, Maryland. I am presently on leave to work on national health care policy as the Senior Economist for health care on the White House Council of Economic Advisers. My qualifications have previously been stated in my Declaration of Mark G. Duggan, Ph.D., In Support of the United States' Motion for Partial Summary Judgment and in Opposition to Defendants' Motions for Partial Summary Judgment.<sup>1</sup>

2. On April 23, 2009, I provided a Rebuttal Report of Mark G. Duggan, Ph.D, in which I responded to various arguments set forth in the Expert Report of Professor W.

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<sup>1</sup> This document is Exhibit 41 to the Declaration of George B. Henderson, II Submitting Common Exhibits in Support of Motions for Partial Summary Judgment (Master Dkt #6310-53, Subcategory #308-53).

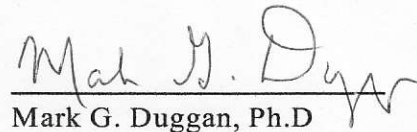
David Bradford, Ph.D. Attachment A is a true copy of my Rebuttal Report. The Rebuttal Report correctly states my opinions, and the factual statements in it are true and correct to the best of my knowledge.

3. On January 19, 2010, I provided a short supplement to my expert report, in which I replied to, and pointed out errors in certain arguments presented in Professor Bradford's report. Attachment B is a true copy of my January 19, 2010, supplement. The supplement correctly states my opinions, and the factual statements in it are true and correct to the best of my knowledge.

4. In footnotes 7 and 8 to my January 19, 2010, supplement, I refer to several publications. True and correct copies of these (or selected portions) are attached as Attachments C - E as follows<sup>2</sup>:

- C. Region C DMERC Medicare Advisory, Spring 2006 (Palmetto), cover page and pp. 28-29;
- D. LCD [Local Coverage Determination] for Nebulizers (L11499), Region A (2005) (see pp. 18-19); and
- E. Spring 2005 Region C DMERC DMEPOS Supplier Manual (part 21 (see especially pp. 21.3 - 21.4)).

I swear under the penalties of perjury that the forgoing statements are true and correct.

  
Mark G. Duggan, Ph.D

Executed this 9th day of February, 2010

<sup>2</sup> Page numbers have been added to Attachment D. The original was unpaginated.

# **Attachment A**



## **Introduction**

In this document I respond to the primary criticisms in Dr. Bradford's report of my January 23, 2009 report, which calculated the difference between what the federal government reimbursed for certain pharmaceutical products provided to Medicaid and Medicare recipients during the 1992 to 2008Q1 period and what the federal government would have reimbursed for the same products during the same period if prices reflective of the actual prices at which Dey L.P. (hereafter Dey) was transacting business had been used for the AWP and WAC of Dey Complaint products.

## **Holding All Else Equal**

One of Dr. Bradford's criticisms of the analysis in my Dey report is that I hold other factors constant when determining the amount that the federal government would have paid if alternative AWPs and WACs had been used for Dey's products when adjudicating claims for the Medicare and Medicaid programs.<sup>1</sup> When estimating the causal effect of one variable on some other variable, it is common practice in applied microeconomics to hold other factors constant and to focus on the direct rather than the indirect effects. For example, in my own previous research on Medicaid managed care that was published in the *Journal of Public Economics* (2004), I estimated the effect on Medicaid expenditures of shifting Medicaid recipients from fee-for-service into managed care while holding other factors constant. To do this, I utilized Medicaid claims and enrollment data to compare spending for the same person before and after they were shifted into Medicaid managed care, and estimated the extent to which average spending changed as a result.

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<sup>1</sup> See, for example, Bradford report page 123; see also report of Lauren J. Stiroh, pages 43-44.

It is indeed possible that the shift from fee-for-service into managed care might have affected enrollment in the program, as some individuals might have decided to enroll in Medicaid or disenroll from Medicaid at different times as a result. This would of course induce a change in Medicaid spending that would not be captured by the analysis described above. Similarly, the state may have elected to change hospital or physician reimbursement if it had not move to Medicaid managed care. However, in this study and in many similar studies by myself and others specializing in applied microeconomic research, I held these other factors, which represented two of the many possible indirect effects of the policy change, constant.<sup>2</sup>

Of course the details of my 2004 study differ in certain respects from the application considered in my report. But once one opens up the possibility of indirect effects, as Dr. Bradford does in his own report, it is important to remember that many of the most plausible indirect effects would *increase* rather than reduce the damages summarized in my report. Additionally, estimates of the magnitude of each one of these indirect effects will in many cases be driven by the researcher's often untestable assumptions and his/her subjective judgments about which factors to allow to change. For example, would pharmacies have reduced their purchases of Complaint products in response to the more truthful AWP, and if so by how much? Would the more truthful reporting by Dey have caused its competitors to report more truthful prices? Would state Medicaid agencies have raised their dispensing fees in response to lower AWP for 26 out of the 25,000 or so NDCs covered? By how much would they have raised these dispensing fees? How much would the federal government's FUL prices or state governments'

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<sup>2</sup> Other examples of studies that aim to isolate the causal effect of one variable on one or more other variables by holding other factors constant abound in economics. See, for example, Evans and Snyder (2006) regarding the effect of income on mortality, Levitt (1997) for the effect of police on crime rates, Gruber and Poterba (1994) for the effect of tax incentives on health insurance coverage, Angrist and Evans (1998) for the effect of the number of children on maternal labor supply, and Card and Krueger (1994) for the effect of the minimum wage on employment. In these studies and many related ones, the authors focus on the direct effect of the variable of interest rather than the many possible indirect effects.

MAC prices have changed as a result of the alternative AWP and WACs?<sup>3</sup> Would these lower AWP and WACs have caused the federal government and state governments to implement their FUL and MAC prices sooner? Would Medicare utilization have increased because of the lower consumer co-pay on J-code products, and if so by how much?

All of these factors and many more become potentially relevant once one opens up the possibility that more truthful price reporting by Dey would have had indirect effects. The direct effects that I consider in my report, which hold other factors constant, are based on claims that were actually paid by the Medicaid and Medicare programs, and demonstrate a significant effect on federal expenditures, state expenditures, and out-of-pocket costs for Medicare recipients.

### **Medicaid Utilization**

Dr. Bradford argues (on pages 50-51 of his report) that if Dey had reported prices that were more reflective of actual transaction prices for Complaint products, pharmacies would not have purchased Dey's products because it would not have been profitable for them to do so. However, Dr. Bradford does not offer credible empirical evidence to support the claim that this would have a material impact on my findings. And indeed if this were true, then it would serve to increase rather than reduce the total value of DIFFERENCE, because the federal government would not have paid anything for those claims because they would not have been submitted.

Furthermore, if one were to consider the effect that alternative AWP for Dey's Complaint products would have had on utilization for these products, it is instructive to consider a real-world example that to some extent mimics the AWP changes that I consider in my report. In 2000 and 2001, substantially lower AWP were implemented for Abbott Complaint products described in my June 19, 2008 Abbott report. For example, the AWP for Abbott's Vancomycin

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<sup>3</sup> In some instances, one might consider this a direct effect, but I do not examine this issue in my analysis.



653301 product fell by 77 percent, from \$76.43 to \$17.73, while similarly large AWP declines occurred for Abbott's other Complaint products, and there were no corresponding changes in dispensing fees. In the subsequent three years, little change was observed in the use of these same Abbott products. For example, the total number of prescriptions for Abbott's Complaint products actually increased by 5 percent from the fourth quarter of 1999 until the fourth quarter of 2003.<sup>4</sup> Thus even with this massive change in AWPs, there was not a correspondingly significant change in the utilization of these products, thus undermining the claim that utilization of Dey's Complaint products would have plummeted if they had reported more truthful AWPs.

### **Medicaid Dispensing Fees**

A related point that Dr. Bradford makes on pages 52-59 of his report is that, if Dey had reported more truthful AWPs for Complaint products, the state Medicaid agencies would have adjusted their dispensing fees to offset the reduction in pharmacies' ingredient cost profits. Once again, Dr. Bradford offers little credible evidence to support this claim. In considering the validity of this point, it is important to note that Dey's Complaint products accounted for less than 0.3 percent of Medicaid prescription drug spending in every year considered. Thus the effect on pharmacies' overall reimbursement would have been very small, undermining the claim that this would have necessitated across-the-board increases in pharmacy's dispensing fees.

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<sup>4</sup> An examination of the utilization data does suggest a modest effect of the revised prices on utilization. More specifically, from 1999Q4 to 2000Q4, the number of prescriptions for Abbott's Complaint products increased from 94,777 to 105,034 after having risen steadily in the preceding years along with Abbott's AWPs. By 2003Q4, this had declined to 99,476, suggesting that the lower ingredient cost reimbursement did lead to a modest reduction in utilization of Abbott products below what it otherwise would have been. It is also worth noting that there may be a stronger response by pharmacies to changes in published AWPs when they are increasing than when they are declining, as once they have paid the fixed cost to establish a contract with Abbott they might stick with it. Indeed, asymmetric price responses have been reported for other sectors, such as the practice of retail gas outlets to raise prices more quickly in response to increases in the price of crude oil than to lower them when crude oil prices decline (Borenstein, Cameron, and Gilbert, 1997), which has been dubbed the "rockets and feathers" phenomenon.

It is once again instructive to consider the Abbott example cited above when considering this issue. An examination of the state-specific dispensing fees indicates that there was not a large increase after the change in Abbott and other firms' AWP's that occurred in 2000 and 2001 when states implemented the DOJ prices. More specifically, there were 33 states (excluding Ohio) that used the DOJ prices, with 19 holding their dispensing fees fixed at that time, 5 reducing their dispensing fees, and 9 increasing their dispensing fees. Among the fourteen that changed dispensing fees<sup>5</sup>, the average change was actually less than zero (-\$0.14), as the dispensing fee reductions for the 5 that reduced more than offset the effect of the 9 that increased. Additionally, this coincided with substantial price changes for hundreds more products with much greater Medicaid spending than is considered in my report.

Dr. Bradford however implies that one must instead consider an across the board change in price reporting for all of the approximately 25,000 pharmaceutical products currently being reimbursed by the Medicaid program when evaluating the appropriateness of the transaction-based AWP's for the 26 Complaint NDC's described in my report.<sup>6</sup> Of course, this would require knowledge of the spread between AWP's and actual transaction prices for all 25,000 of these products. And this would include not only generic products but also brand products, for which my previous research with Dr. Scott Morton in the Quarterly Journal of Economics (2006) on Medicaid drug reimbursement suggests that Medicaid's average AWP-based reimbursement amounts per prescription are a quite reliable guide to actual average prices. Given that brand products account for more than 80 percent of Medicaid drug spending, if one were to scale actual average prices by 1.25 for all pharmaceutical products' AWP's, it seems plausible that pharmacies would on average have higher ingredient cost reimbursement overall. Put simply, the

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<sup>5</sup> It is worth noting that the timing of the dispensing fee change and the implementation of DOJ prices did not in all cases line up exactly, though I restrict to changes that occurred in 2000 and 2001.

<sup>6</sup> See also Stiroh report, page 44.

spreads that existed for Dey's Complaint products are unlikely to be representative of the spread for all pharmaceutical products.

In evaluating the merit of Dr. Bradford's claim, it is also instructive to consider the increase in the use of MAC and FUL prices by state Medicaid programs during the past decade. An examination of dispensing fees during the same time period provides no evidence to suggest that there was a sea change in dispensing fees that accompanied the reduction in ingredient cost reimbursement for generic products. In just five out of twenty-three cases when a state implemented a MAC program during the time period of interest did it also increase its dispensing fee around the same time, with an additional two states lowering their dispensing fee.<sup>7</sup> The average change in the dispensing fees among these twenty-three states was just nine cents, thus undermining the theory that significant changes in dispensing fees would have occurred if Dey had reported more accurate prices for its AWP's and WAC's.

Additionally, it is very likely that the use of the alternative AWP's that I describe in my report would have substantially lowered the state MAC prices and/or the federal FUL prices in a similar fashion to the effect of more truthful AWP's on Medicare reimbursement. This would reduce reimbursement not only for Dey's products but for some of its competitors' products in the same drug group as well. As I mention in my report, this would almost certainly have led to a substantial increase in the total value of DIFFERENCE. However, Dr. Bradford omits any discussion of this plausible effect in his report.

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<sup>7</sup> It is once again worth noting that the timing of the dispensing fee change and the implementation of SMAC prices did not in all cases line up exactly.

### **Many Plausible Indirect Effects Raise Rather than Reduce DIFFERENCE**

In pointing to the possible indirect effects of the alternative AWP's that I calculate from Dey's transaction data, which are just 25 percent greater than actual average pharmacy prices rather than the 500 percent or 1000 percent greater as were those reported by Dey, Dr. Bradford points only to those indirect effects that would lower the total value of DIFFERENCE in my report, such as the increase in Medicaid dispensing fees. But as noted above, Dr. Bradford offers no empirical evidence to support his theory that utilization would have plummeted or that dispensing fees would have surged in response to more accurate published prices for Complaint products. Dr. Bradford also omits any consideration of those indirect effects that would lead to an increase in the value of DIFFERENCE, thus essentially cherry picking those indirect effects that go in the direction that is favorable to Dey.

### **An Analogy to Medicaid Hospital Reimbursement**

In considering the criticism of the "all else equal" assumption that I make in my report, it is useful to consider an analogy. Suppose that a hospital could not profitably serve Medicaid patients at a state's current reimbursement rates. It could then contact the state Medicaid agency and relay this concern to government officials, with this possibly leading to an increase in hospital reimbursement. Or it could choose to serve these Medicaid patients even though it would be unprofitable for them to do so, recognizing that Medicaid patients are on average unprofitable for hospitals, nursing homes, physicians, and many other health care providers as well (Gruber, 2003). Or it could simply decide not to serve the Medicaid population. Alternatively, the hospital could decide to go an entirely different route by "upcoding" the Medicaid patients' diagnoses to more serious ones (thus boosting its revenues) or by reporting

more services on the Medicaid claims than were actually performed. This might be motivated by a concern for Medicaid patients or simply by a desire to increase hospital profits.

If this hospital was caught in the act of upcoding or filing false claims, it might then be called upon to pay damages equal to the difference between the actual amount paid and the amount that would have been paid if it had not upcoded or submitted false claims. The hospital might then assert that if it had been truthful, it would not have been able to serve Medicaid patients, and thus utilization at this hospital would have been zero. Using Dey's argument, this would imply no damage to the government, as these patients would simply have been treated elsewhere and Medicaid revenues at the hospital would have been zero. Or this hospital might argue that if it had been truthful, it would have advocated strongly for higher reimbursement from the state Medicaid agency to make it more profitable for them to treat these patients. Using Dey's reasoning, the savings one would then estimate using the proper diagnoses (rather than the upcoded ones) or the correct number of claims for Medicaid patients would be misleading. But this is indeed extremely speculative, as it is unclear that such a reimbursement change would have occurred and the magnitude of this change would be impossible to estimate with any precision, as it would reflect the outcome of a negotiation between the hospital and the state Medicaid agency.

Unfortunately for this hospital and by analogy for Dey, none of these arguments change the fact that they could have been truthful (or less misleading) but elected not to be. The available evidence suggests that Dey aimed to use these extremely inaccurate and inflated AWP's to its financial advantage in an effort to improve the company's market position and thus its revenues. I am unaware of any evidence that Dey inflated its published prices out of a concern about access for Medicaid recipients. And even if one assumes that the hospital in my analogy

or Dey in this case had altruistic motives to ensure access for Medicaid recipients, it does not appear to justify providing extremely inaccurate information to the government.

### **Applying the Massachusetts Medicaid Algorithm to All States and to Medicare**

Dr. Bradford further argues that each state Medicaid agency had some latitude to choose its adjudication algorithm. He then points to the fact (on pages 181-182) that Massachusetts used WAC for its reimbursement whereas most other states did not. As I demonstrate in my report, the ratio of DIFFERENCE to total Medicaid spending in Massachusetts is much lower than in other states given that Dey's WACs are on average less inflated above actual prices than were its AWP. Dr. Bradford states that every state could have used the Massachusetts algorithm, and then uses this same algorithm (rather than the one that each state was actually using) when calculating the effect of alternative WACs on each state's Medicaid reimbursement for Dey's Complaint products (Bradford report at pages 133-135).

The value of DIFFERENCE with even this one adjustment would inevitably be much lower in each state, but this assumption is clearly inappropriate. State governments had the adjudication algorithms that they did, with most relying primarily on AWP rather than WACs, and thus Dey's extremely inflated AWP led to substantial damage to the federal government and to individual state governments. Indeed by Dr. Bradford's line of reasoning, if one state implemented a MAC that was less than Dey's transaction-based AWP (125 percent of the average pharmacy indirect price), then the value of DIFFERENCE for this product would be zero in all states, because clearly other states could have made this same decision as well.

Dr. Bradford then uses this same line of reasoning for Medicare, which he argues could have used WAC prices rather than AWP in the J-code arrays when determining the per-unit

allowed amounts. He then assumes this in his own empirical analyses, which for the reasons mentioned above, is clearly inappropriate. Medicare used pharmaceutical products' AWP when calculating allowed amounts for J-code claims, and Dey's decision to provide extremely inaccurate information for its AWP led to significant damage to the government.

### **Consideration of Cardinal Wholesaler Data**

Dr. Bradford also criticizes my use of Dey's indirect data, which captures sales by wholesalers to pharmacies and other health care providers that have contracts with Dey. He argues that, given that these wholesalers make some sales off-contract, the average prices and other price statistics that I calculate are inaccurate because these transactions would not be included. He instead advocates the use of data from Cardinal, which according to Table 9 of my report is the second largest wholesaler in Dey's indirect data, accounting for 20 percent of sales.

One limitation of this data is that it represents sales by just one wholesaler, and thus what the calculation gains in capturing off-contract sales it could plausibly lose by happening to be a high or low-priced wholesaler. Indeed, Dr. Bradford provides little evidence to suggest that Cardinal's prices are representative of those at which other wholesalers sold Dey's Complaint products. Nevertheless, my examination of this data indicates that the alternative NDC-quarter-specific AWP that I utilize, which are equal to 125 percent of the pharmacy-specific indirect price, are on average substantially greater than the average price at which this one wholesaler sold Complaint products. In other words, the actual average price at which Cardinal sold Dey's Complaint products is on average lower than the alternative AWP that I use in my empirical analyses, which are equal to 125 percent of the average pharmacy indirect price. This suggests

that if I had used Cardinal's average prices in my analyses as the alternative AWP, my findings for the total damage to the federal government would have been higher.

Thus while it is true that prices for off-contract sales are on average somewhat higher than on-contract sales, there are not sufficiently many of these transactions nor is the price difference sufficiently large to have an appreciable effect on average wholesaler prices for Dey's Complaint products. This is perhaps easiest to see by considering an example. As I explain in my report, Dey's 49502069703 Albuterol Sulfate product accounts for more Medicaid sales than any other Complaint product. The average price for the pharmacy classes of trade in Dey's indirect data for this product from 1995Q2 to 2004Q3 was \$6.22. Thus the alternative AWP that I use is on average \$7.77, which is 25 percent greater than the actual average price. In comparison, the actual average price in the Cardinal data for pharmacy retailers was \$6.55, which is substantially lower than the transaction-based AWP that I calculate. Both of these prices are almost 80 percent lower than the AWP of \$30.25 that was in effect for this product during the same period. A similar pattern is present for the largest Ipratropium Bromide NDC, with an average price of \$11.70 (thus an alternative AWP of \$14.63) versus a Cardinal average of \$12.09. These prices are on average approximately 73 percent lower than the AWP of \$44 that was in effect for this product during the same period.

An additional point worth noting regarding this data is that Dey presumably did not have access to comprehensive information on wholesalers' off-contract prices. In light of this, it is not obvious how these off-contract sales by wholesalers could have affected Dey's conduct in reporting its AWP and WACs.



## Medicare Dispensing Fees

Dr. Bradford also argues on pages 117-120 that dispensing fees would have increased for Medicare claims if the alternative AWP had been used for Dey's Complaint products. As evidence for this, he points to the fact that the Medicare Modernization Act (MMA) changed reimbursement for inhalation products from 95 percent of the median AWP in 2003 to 106 percent of the average sales price (ASP) by 2005, and that CMS subsequently increased the dispensing fee from \$5 to \$57 for the first 30-day supply and \$33 and \$66 for subsequent 30-day and 90-day supplies, respectively.<sup>8</sup>

There are a number of significant problems with this approach, as one must incorporate other elements of the methodology that changed to accurately capture the effect of the revised method for determining Medicare allowed amounts. First, one must focus not just on the pharmacy classes of trade, which tend to have higher prices, when calculating average prices, but instead consider customers in all classes of trade. Second, one must change the scaling factor for the transaction-based average prices from 1.25 to 1.06. Third, one must use a dispensing fee that applies to all prescriptions that cover a 30-day or 90-day supply of inhalation drugs<sup>9</sup> instead of the \$5 dispensing fee that was applicable to each prescription. And finally, one must assume that all firms (not only Dey) would have reported their average sales price accurately.<sup>10</sup> This would cause the median to fall substantially because all firms' reported prices would be adjusted. And then, it would be appropriate to assign responsibility according to each firm's market share.

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<sup>8</sup> As discussed above, Dr. Bradford also assumes that Medicare should have used WACs instead of AWP, and assumes that they did this in his analyses. But for the reasons cited above in the Massachusetts example, it is inappropriate to assume that the law was different than what was in effect.

<sup>9</sup> See 70 Fed. Reg. 70334 (November 21, 2005) (section 414.1001 (c)), and response to comment at 70 Fed. Reg. 70231 (rejecting comment proposing a per prescription fee).

<sup>10</sup> Under the MMA, the allowed amount is based on an average of the ASPs for the NDCs within the J-code. In changing the dispensing fee, CMS assumed that all pertinent manufacturers would report their ASPs accurately. See 70 Fed. Reg. 47488, 47549 (August 5, 2004).

An examination of the Medicare claims data for Ipratropium Bromide indicates that these adjustments, which would serve to increase the value of DIFFERENCE, would in all likelihood more than offset the effect of the revised dispensing fee on the total value of DIFFERENCE. To shed light on this issue, it is useful to consider the following. Prior to the MMA, the average dispensing fee per claim for Medicare claims for Complaint J-codes was approximately \$3.71 during the study period, which was lower than \$5 because there were in many cases multiple claim line items associated with one dispensing fee. For the purposes of this analysis, I assume that the average claim in this pre-2004 period covered 30 days.

To estimate the analogous dispensing fee per 30-day period in 2006, I assume that the average user had twelve 30-day prescriptions during the year, which would yield an average dispensing fee of \$35.<sup>11</sup> Of course, Medicare pays just 80 percent of the cost of the typical claim, and so the effective increase in the share of the per-claim dispensing fee was approximately \$25 (80 percent of the difference between \$35 and \$4), which is substantially lower than the average per-claim value of DIFFERENCE in either of the combined Dey and Roxane scenarios. If one applied this \$25 increase to all 12.836 million claims, Medicare spending would have increased by approximately \$321 million.

Now suppose that 106 percent of Dey's average sales price for all customers was used for adjudicating all claims. Ignoring for a moment the dispensing fee issue, this would lead to a much higher value of DIFFERENCE than is reported for any scenario in Table 35 of my original

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<sup>11</sup> There are three sources of uncertainty with this comparison in dispensing fees in the pre-2004 period versus the post-MMA period. First, it seems plausible that many Medicare recipients would have filled 90-day prescriptions in the 2006 period, which would lead to a lower average dispensing fee per month during this period. Second, some users may not have filled the prescription in all twelve months, which would lead to a higher average dispensing fee in those months with a prescription. And finally, the typical prescription in the pre-2004 period may have been for a period of less or more than one month. To the extent that the prescriptions were on average less than a month in the pre-period, the per-month dispensing fee would have been even higher. It should also be noted that Medicare now pays just one dispensing fee for the applicable period regardless of the number of drugs dispensed. In contrast, before 2004, the dispensing fee was paid for each prescription.

report for the reasons outlined above. More specifically, the total value of DIFFERENCE would be \$1.510 billion, as shown in Table A, which is more than \$400 million greater than the total value of DIFFERENCE in the Dey and Roxane combined scenario that does not include Novaplus. This would more than offset the \$321 million caused by the dispensing fee increase above. If one subtracts the \$321 million from the \$1.510 billion, the revised DIFFERENCE is \$1.189 billion. Using Dey's market share of all Ipratropium Bromide Medicaid claims in each quarter, I calculate that Dey's share of this revised DIFFERENCE would be \$642 million.<sup>12</sup> This is substantially greater than the \$340 million Dey share of DIFFERENCE for the combined Dey and Roxane Novaplus scenario in the February 6, 2009 supplement to my initial Dey report that uses Dey's relative market shares and just 19 percent lower than Dey's \$790 million share of the DIFFERENCE in the combined Dey and Roxane no-Novaplus scenario.<sup>13</sup>

One must of course also repeat this exercise for the Albuterol Sulfate J-code claims. Once again, the revised dispensing fee would increase expenditures by approximately \$347 million (\$25 multiplied by the 13.873 million Albuterol Sulfate claims). But the total value of DIFFERENCE using 106 percent of Dey's average sales price would increase from \$2.251 million to \$1.056 billion, as shown in Table B. This would once again much more than offset the effect of the increase in dispensing fees, and Dey's share of this total DIFFERENCE based on its market share of Albuterol Sulfate Medicaid claims would be \$158 million.<sup>14</sup> Adding this to the \$638 million calculated above, Dey's total DIFFERENCE of \$796 million (which incorporates

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<sup>12</sup> As shown in Table A, Dey's share of the \$1.510 billion is \$816 million. Its share of the \$321 million is \$174 million given its 54.1 percent share of all Ipratropium Bromide claims.

<sup>13</sup> In these latter two cases I use Dey's share of all Dey and Roxane claims rather than its overall share of all Ipratropium Bromide claims. When allocating responsibility in my original report, I applied Dey and Roxane's relative market shares because the total DIFFERENCE was a function of the inflated AWP's of only Dey and Roxane, to the exclusion of their competitors. However, when allocating responsibility under a methodology that considers the impact of all market participants, it is appropriate to apply Dey's share of the entire market, since all market participants share responsibility.

<sup>14</sup> As shown in Table B, Dey's share of the \$1.056 billion is \$248 million. Its share of the \$347 million is \$90 million given its 25.8 percent market share of Albuterol Sulfate claims.

the rise in dispensing fees) would be greater than any of the values that I calculate in the February 6, 2009 supplement to my report.

To sum up, if one applies Dr. Bradford's methodology by increasing the Medicare share of the dispensing fee by \$25 per claim while reducing allowed amounts to 106 percent of the average sales price, the total value of DIFFERENCE would increase substantially. Put simply, the lower allowed amounts resulting from the 106 percent of the average sales price would more than offset the effect of the increase in dispensing fees, leading to a greater impact on Medicare spending. And this would of course also lead to substantially greater out-of-pocket expenditures for Medicare recipients, who bear 20 percent of the cost of these claims.

Despite the higher value of DIFFERENCE, for the same reasons that I outlined above regarding Dr. Bradford's application of the Massachusetts Medicaid algorithm to other states, it is not appropriate to change the adjudication methodology that the government used. During the time period considered, which includes through and including 2003Q4, the federal government did not use 106 percent of the average sales price and the higher dispensing fee but instead used the methodology that I utilize in my report.

### **Within State Extrapolation**

For my Medicaid analyses, I utilized claims data from state Medicaid agencies for 14 states. These 14 states account for 63 percent of all claims for Dey's Complaint products.<sup>15</sup> The reason that these states account for such a large share of claims is that I utilized state claims data for the states with the largest number of claims, including California, Florida, and New York, but did not analyze the states with the smallest number of claims, such as Vermont, Wyoming, and the District of Columbia.

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<sup>15</sup> As discussed in my report, I excluded Arizona, Ohio, and Texas from the analysis.

In certain periods for each of these 14 states, I did not have complete state claims data, and thus utilized either SMRF/MAX/MSIS claims data from CMS or aggregate SDUD data from CMS. More specifically, for 82.1 percent of the 10.78 million claims for these 14 states I used state Medicaid claims data, while I used SMRF/MAX/MSIS claims data for 8.9 percent, and aggregate SDUD data for an additional 9.0 percent. The advantage of using each state's own claims data when extrapolating to those NDC-quarters when I do not have state claims data is that these NDC-quarters will typically share the same adjudication methodology and provider characteristics as in the NDC-quarters for which I do have state claims data. This is depicted graphically in Figure A, with the corresponding expenditure shares in Figure B.<sup>16</sup>

Dr. Bradford criticizes my analyses for these 14 states when I do not utilize state claims data as being unreliable. As I make clear in my report, my algorithm during those periods when I do not have state claims data is quite conservative, as I adjust if the spread between actual and reported prices is lower (thus reducing the DIFFERENCE) but do not adjust if the spread between actual and reported prices is higher. For example, suppose that the ratio of DIFFERENCE to Medicaid spending is 0.5 for an NDC-quarter in 1995Q1 and that this is the first quarter for which I have claims data. If the spread between the AWP and the actual average price is lower in 1994Q4 then I adjust this 0.5 ratio down accordingly. However, if the spread is higher, which would generally imply a ratio higher than 0.5, I do not scale this upward.

Nevertheless, to probe on the validity of Dr. Bradford's criticism, I took the following approach. For each state I pretended that the state Medicaid claims data started one year later and terminated one year earlier than they actually did. I then utilized the SMRF/MAX/MSIS claims data if it was available and otherwise used the SDUD data to estimate the total value of

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<sup>16</sup> The red area in the middle of the bars represents the amount of all claims or expenditures in each year that use a within-state extrapolation.

DIFFERENCE during these one-year periods. My findings indicate that the total value of DIFFERENCE across these 14 states is actually substantially *higher* when I use the state claims data than when I utilize these alternative sources of data.<sup>17</sup> It therefore appears that, if anything, the fact that I do not have complete Medicaid claims data for all 14 of these states serves to reduce rather than to increase the total value of DIFFERENCE.

### **Across State Extrapolation**

Dr. Bradford criticizes my use of data for just 14 of the 48 states considered and the methodology that I use to estimate the total value of DIFFERENCE in the remaining 34 states. As mentioned above, these states account for a disproportionate share of all Medicaid claims for Complaint products (63 percent), as they include the large states such as New York and California while excluding states with relatively few claims such as Wyoming and Vermont. Additionally, my coverage with state claims data is most complete during those years with the highest number of Medicaid claims and Medicaid expenditures. This is depicted graphically in Figures A and B for Medicaid claims and expenditures, respectively.<sup>18</sup>

In considering the validity of the extrapolation, it is worth noting that the two groups of states share many common features. All of the states reimburse for the same Dey Complaint drugs, and all of the states are subject to the same federal regulations. All of the states use published prices when adjudicating claims and the vast majority of the states use the AWP. The fraction of states in the two groups that use the WAC is similar and the scaling factors for these prices are on average similar between the two groups. All of the states in the two groups have a

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<sup>17</sup> If I pretend that the state claims data starts one year later and finishes one year sooner for each state, the total value of the federal DIFFERENCE for these 14 states falls from \$100.793 million to \$96.484 million.

<sup>18</sup> The beige bars at the top represent the amount of claims or expenditures in the year for the 34 states.

“lower of” methodology except for New York, and all of them use the federal upper limit (FUL) prices that are published by the U.S. Department of Health and Human Services.

It is also important to remember that often in applied microeconomic research there is no data for those entities to which the extrapolation is being performed. However, in this setting I am utilizing multiple sources of detailed information regarding Medicaid claims for the Complaint products for those states to which I am extrapolating. Additionally, I do not extrapolate to any state or time period in which I do not have CMS claims data or SDUD data.

Furthermore, it is indeed common practice in applied microeconomic research to use data for a subset of the entire population when estimating the effect for the full population. For example, the seminal research on the effect of the unemployment insurance (UI) program, including work by Bruce Meyer that was published in *Econometrica* in 1990, utilized administrative UI data for just 12 states to estimate the effect of the UI program on trends in the national labor market. Additionally, research by Adams, Gruber, and Newhouse published in the *Journal of Human Resources* in 1997 examined the effect of physician fee changes in Tennessee while using Georgia as a control to shed light on the effect of Medicaid physician reimbursement on the treatment of Medicaid recipients. Additionally, it is common practice in applied microeconomic research to use data for a sample that may not be fully representative to estimate results for the U.S. as a whole. For example, recent work published by Jon Gruber and David Rodriguez in the *Journal of Health Economics* in 2007 utilizes data for a subset of physicians to estimate the amount of uncompensated care that physicians in the U.S. provide.

When considering the algorithm that I use in my analysis, it is important to emphasize that I use data for up to 14 states for more than one thousand NDC-quarter combinations when estimating the value of DIFFERENCE for these same NDC-quarter combinations in each of the

remaining states. My examination of the adjudication algorithms used by these states, their reimbursement per claim, and so forth indicates that they are indeed very similar to the 34 states. Indeed, the most striking disparity is that the state of New York had an adjudication algorithm that led to a much lower value of DIFFERENCE because it used the FUL regardless of the product's AWP. This will tend to pull down the per-claim value of DIFFERENCE for the 14 states that I consider and thus lead to a conservative estimate for the remaining 34.

It is worth noting that the 14 are not a random sample of the initial 48, but this is because I focused attention on the largest states to obtain the maximum amount of precision. Put simply, it is more important to the total value of DIFFERENCE to be as accurate as possible for the state of New York, with more than \$64 million in Medicaid spending on Complaint products, than it is in the state of Vermont, which spent less than \$1 million on these same products.

Nevertheless, it is instructive to consider how the total value of DIFFERENCE might have changed if I had utilized claims data for each of the remaining 34 states. To do this, I repeated the algorithm that I used for New York, California, and the other states for Wisconsin and South Carolina, two states with relatively high spending for which I did have state claims data. In the case of Wisconsin, my findings indicate that the federal share of DIFFERENCE is \$2.92 million, versus the \$2.57 million estimated in my initial report. Similarly, for the state of South Carolina, my results indicate a total federal DIFFERENCE of \$2.35 million, versus the \$2.34 million in my initial report. These results provide strong support for the methodology that I used to estimate the total value of DIFFERENCE in the remaining 34 states.<sup>19</sup>

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<sup>19</sup> These values differ from those reported by Dr. Bradford in his report because, in contrast to my analyses, he drops those claims on which the provider charged amount is paid and drops claims and SDUD data outside of the period with state claims data. He is therefore considering fewer claims and thus it is not surprising that his DIFFERENCE is lower than the one that I calculate.



### **Medicare DMERC-Quarter Combinations with a Missing Array**

Dr. Bradford (in paragraph 308) also criticizes my analyses for Medicare because I do not have arrays for certain DMERC-quarter combinations, and thus interpolate the array from the ones in the quarters immediately before and after that quarter to estimate the array that was in effect. Specifically, I do not have array information for 9 of the 120 (7.5 percent) DMERC-year-quarter combinations that I consider for Ipratropium Bromide and for 17 of the 135 DMERC-year-quarter combinations for Albuterol Sulfate. An examination of the arrays reveals that this is appropriate because the arrays are quite stable over time, with every one of the arrays that I observe having at least two Dey products. Thus there is no basis for omitting damage calculations from those DMERC-quarter combinations in which no array is present because the available evidence indicates that Dey is always in the array.

In every case when I am missing an array, I take the conservative approach of using the adjacent array that would result in the lower value of DIFFERENCE. The most common approach in applied microeconomic research – to linearly interpolate when missing data for a certain time period – would lead to higher values of DIFFERENCE and thus to results that would be less favorable for Dey. And an examination of the 8 gaps in the arrays indicates that the before and after arrays are the same in 3 cases and are very similar in the other 5 cases. Additionally, if I compare the allowed amount that I use in these 8 cases with the corresponding allowed amounts for the other DMERCs, it is generally higher which implies a lower value of DIFFERENCE. Put simply, my algorithm for those DMERC-quarter combinations in which I am missing an array is conservative and will lead to a total value of DIFFERENCE that is lower than would result if I had the arrays in every DMERC-quarter.

### **Average versus 95<sup>th</sup> Percentile Prices**

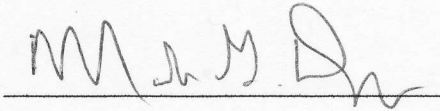
On page 123 of his report, Dr. Bradford also criticizes my use of Dey's average prices, and instead proposes the use of 95<sup>th</sup> percentile prices. In considering this issue, it is important to note that virtually all state Medicaid programs and the federal Medicare program use average price information. When the Medicare program switched to an ASP-based methodology in 2005, it continued to rely on average price information. Notably, when CMS issued regulations implementing the ASP methodology, it commented that "it is true for all payment systems based on averages that the payment amount may not equal a specific provider's cost for every service."<sup>20</sup> Furthermore, the alternative AWP's that I calculate are equal to 125 percent of Dey's actual average NDC-quarter-specific prices to pharmacies for Complaint products. As I demonstrate in Table 13B of my January 23, 2009 report that summarizes my Medicaid analyses for the state of New York, 125 percent of the average price leads to a lower value of DIFFERENCE than results when I instead utilize the 95<sup>th</sup> percentile price. Put simply, this scaled average price tends to exceed the 95<sup>th</sup> percentile price and is therefore more favorable to Dey.

### **Revisions to Calculations for the no-NovaPlus Scenario**

In my original report, I removed the Roxane NovaPlus products from the generic portion of the DMERC-A arrays. I have determined that it is more appropriate to leave Roxane's NovaPlus products in the generic portion of the Medicare DMERC-A arrays and leave their prices unchanged in the no-NovaPlus combined scenario for Ipratropium Bromide. As a result of this, the combined value of DIFFERENCE declines from \$1.103 billion to \$1.093 billion. Dey's share of this DIFFERENCE, using its relative market share, falls as a result from \$790 million to \$782 million. This revision is summarized in the attached Tables 35rev and 38B-rev.

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<sup>20</sup> 70 Fed Reg 70116, 70218 (November 21, 2005).

A handwritten signature in dark ink, appearing to read 'Mark G. Duggan', is written over a horizontal line.

Mark G. Duggan, Ph.D.

April 23, 2009

## **References**

Kathleen Adams, Jonathan Gruber, and Joseph Newhouse (1997), “Physician Fee Policy and Medicaid Program Costs,” *Journal of Human Resources*, 32(4), 611-634.

Joshua Angrist and William N. Evans (1998), “Children and Their Parents’ Labor Supply: Evidence from Exogenous Variation in Family Size,” *American Economic Review* 88, 789-712.

Severin Borenstein, Colin Cameron and Richard Gilbert (1997). "Do Gasoline Prices Respond Asymmetrically to Crude Oil Price Changes?" *Quarterly Journal of Economics*, 112(1), 1997.

David Card and Alan Krueger (1994) “Minimum Wages and Employment: A Case Study of the Fast Food Industry in New Jersey and Pennsylvania,” *American Economic Review* 84.

Mark Duggan and Fiona Scott Morton (2006), “The Distortionary Effects of Government Procurement: Evidence for Medicaid Prescription Drug Purchasing.” *Quarterly Journal of Economics*, 1-31.

Mark Duggan (2004), “Does Contracting Out Increase the Efficiency of Government Programs? Evidence from Medicaid HMOs,” *Journal of Public Economics* 88, 2549-2572.

William N. Evans and Steven Snyder (2006), “The Impact of Income on Mortality: Evidence from the Social Security Notch,” *Review of Economics and Statistics*, 88(3), 482-495.

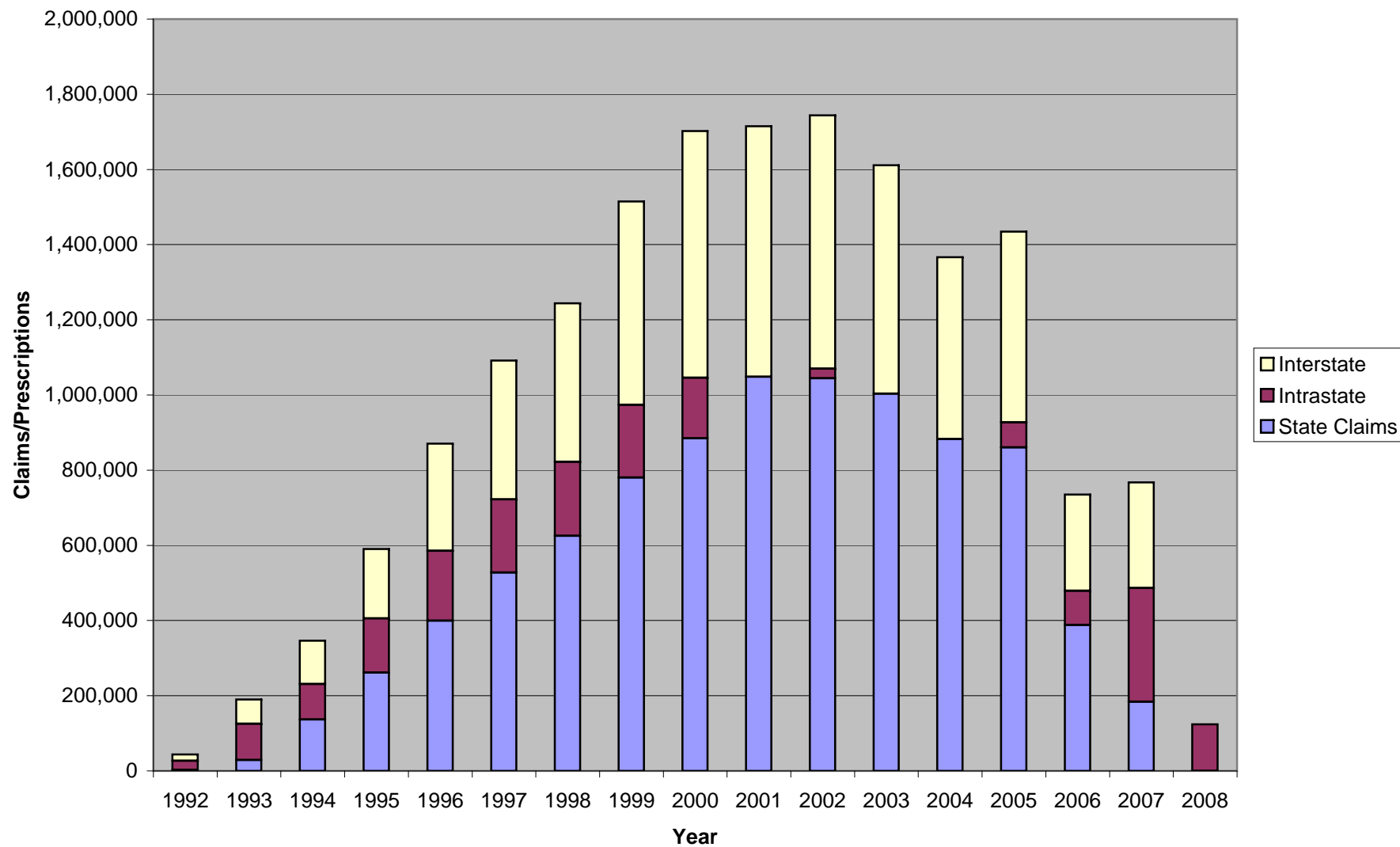
Jonathan Gruber and David Rodriguez (2007), “How Much Uncompensated Care to Doctors Provide?” *Journal of Health Economics*, 26, p. 1151-1169.

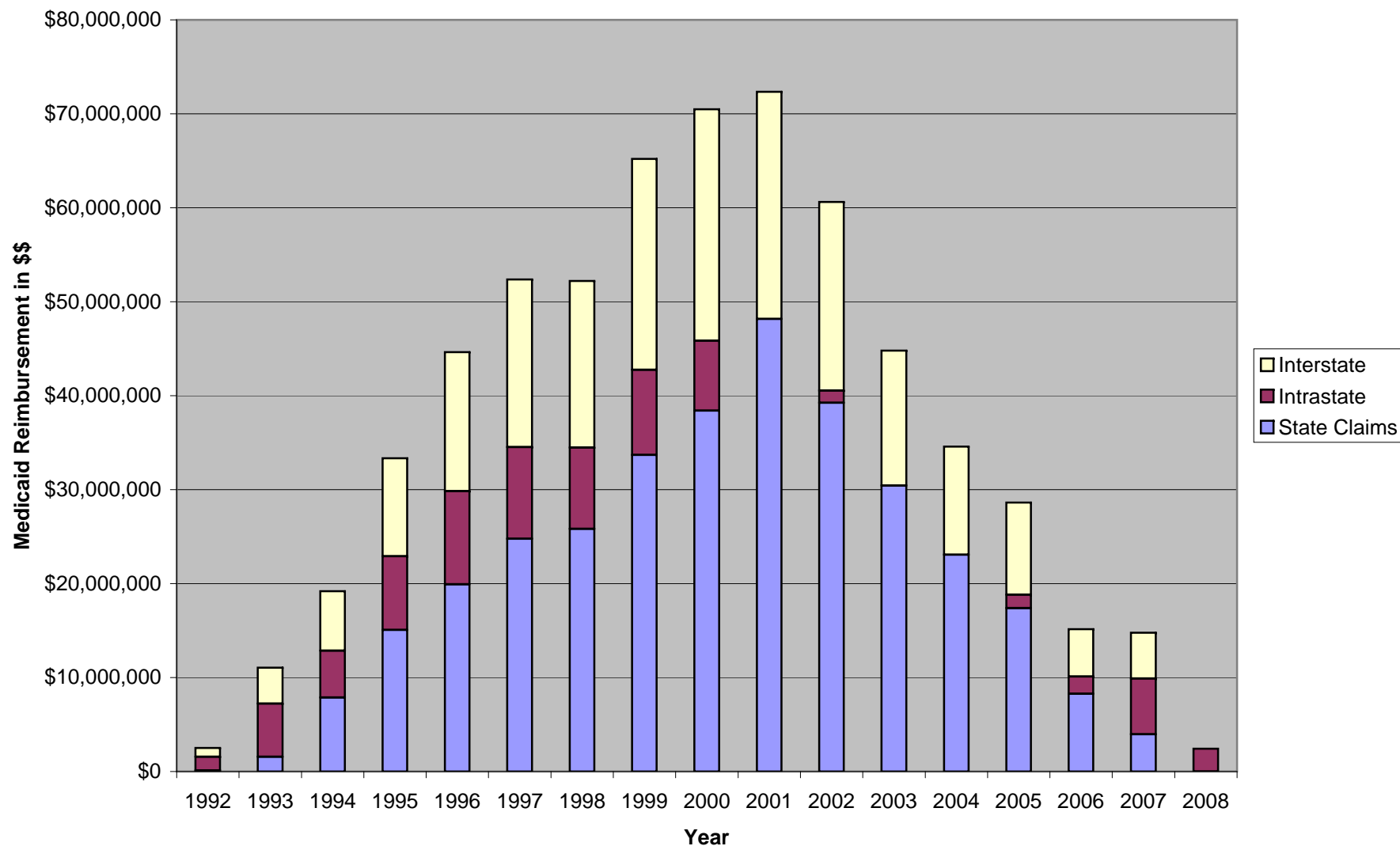
Jonathan Gruber (2003), “Medicaid,” in Robert Moffitt, ed., *Means Tested Transfer Programs in the U.S.* Chicago: University of Chicago Press, pp. 15-77.

Jonathan Gruber and Jim Poterba (1994), “Taxation and the Demand for Health Insurance: The Case of the Self-Employed,” *Quarterly Journal of Economics* 109, 701-733.

Steven Levitt (1997), “Using Electoral Cycles in Police Hiring to Estimate the Effects of Police on Crime,” *American Economic Review* 87(3), 270-290.

Bruce Meyer (1990), “Unemployment Insurance and Unemployment Spells,” *Econometrica* 58, 757-782.

**Figure A: Data Source by Year by Medicaid Claims**

**Figure B: Data Source by Year by Medicaid Spending**

**Table A: Dey Ipratropium Bromide: DIFFERENCE by DMERC and YrQuart**

YrQuart	Total Difference					Dey Share of Difference			
	AdminaStar	CIGNA	DMERC-A	Palmetto	Dey Mkt Share	AdminaStar	CIGNA	DMERC-A	Palmetto
19951	\$79,110	\$0	\$0	\$0	0.0%	\$0	\$0	\$0	\$0
19952	\$0	\$0	\$0	\$0	0.0%	\$0	\$0	\$0	\$0
19953	\$0	\$0	\$0	\$0	0.0%	\$0	\$0	\$0	\$0
19954	\$0	\$0	\$0	\$0	0.0%	\$0	\$0	\$0	\$0
19961	\$0	\$0	\$0	\$124	0.0%	\$0	\$0	\$0	\$0
19962	\$0	\$0	\$0	\$1,047	0.0%	\$0	\$0	\$0	\$0
19963	\$0	\$1	\$0	\$41	0.0%	\$0	\$0	\$0	\$0
19964	\$0	\$1	\$0	\$8	0.0%	\$0	\$0	\$0	\$0
19971	\$0	\$1	\$0	\$0	1.3%	\$0	\$0	\$0	\$0
19972	\$1,988,752	\$1,995,001	\$1,186,828	\$0	15.2%	\$301,562	\$302,510	\$179,963	\$0
19973	\$2,473,686	\$2,476,049	\$1,428,516	\$6,252,373	23.2%	\$574,040	\$574,589	\$331,500	\$1,450,917
19974	\$2,661,877	\$2,793,913	\$1,555,635	\$7,105,177	31.6%	\$840,229	\$881,906	\$491,040	\$2,242,769
19981	\$220,723	\$512,284	\$1,649,617	\$8,864,897	37.5%	\$82,817	\$192,213	\$618,949	\$3,326,176
19982	\$354,121	\$866,939	\$1,900,109	\$10,392,652	43.1%	\$152,514	\$373,377	\$818,348	\$4,475,956
19983	\$4,047,112	\$4,228,397	\$2,119,649	\$12,045,139	45.9%	\$1,856,429	\$1,939,585	\$972,293	\$5,525,160
19984	\$4,173,237	\$4,584,749	\$2,338,419	\$11,864,903	50.9%	\$2,125,382	\$2,334,961	\$1,190,930	\$6,042,661
19991	\$4,460,185	\$4,621,340	\$2,482,564	\$12,632,754	55.0%	\$2,454,365	\$2,543,045	\$1,366,113	\$6,951,592
19992	\$4,869,389	\$4,592,913	\$2,496,072	\$13,214,810	60.2%	\$2,929,283	\$2,762,963	\$1,501,564	\$7,949,647
19993	\$5,096,909	\$4,556,481	\$2,416,120	\$15,114,876	63.4%	\$3,231,166	\$2,888,564	\$1,531,690	\$9,582,020
19994	\$5,395,822	\$6,050,546	\$3,116,304	\$17,935,772	66.9%	\$3,608,644	\$4,046,514	\$2,084,137	\$11,995,173
20001	\$5,640,358	\$6,511,581	\$3,609,683	\$20,054,522	69.2%	\$3,903,436	\$4,506,369	\$2,498,097	\$13,878,824
20002	\$8,727,978	\$8,513,464	\$4,899,933	\$23,047,856	70.2%	\$6,126,372	\$5,975,800	\$3,439,377	\$16,177,830
20003	\$9,386,208	\$8,684,168	\$5,070,216	\$23,958,308	69.4%	\$6,511,736	\$6,024,692	\$3,517,492	\$16,621,214
20004	\$10,631,534	\$9,696,561	\$5,432,990	\$28,401,070	62.9%	\$6,691,588	\$6,103,107	\$3,419,575	\$17,875,902
20011	\$11,672,168	\$10,017,447	\$6,254,167	\$33,009,464	59.7%	\$6,968,581	\$5,980,671	\$3,733,897	\$19,707,490
20012	\$13,664,083	\$11,934,334	\$7,229,912	\$36,387,652	57.0%	\$7,793,961	\$6,807,316	\$4,123,924	\$20,755,431
20013	\$14,426,649	\$12,405,929	\$7,682,866	\$38,549,276	55.5%	\$8,013,114	\$6,890,729	\$4,267,358	\$21,411,746
20014	\$12,881,913	\$10,942,132	\$6,768,388	\$34,188,088	54.4%	\$7,003,926	\$5,949,263	\$3,679,988	\$18,588,143
20021	\$13,258,610	\$14,283,848	\$8,767,096	\$45,093,060	53.2%	\$7,046,968	\$7,591,883	\$4,659,722	\$23,967,017
20022	\$18,861,964	\$15,900,901	\$10,055,872	\$49,037,856	52.0%	\$9,817,011	\$8,275,878	\$5,233,739	\$25,522,536
20023	\$19,889,436	\$16,843,900	\$10,602,920	\$51,935,576	50.3%	\$10,005,349	\$8,473,297	\$5,333,782	\$26,126,108
20024	\$20,689,248	\$17,281,954	\$11,085,417	\$55,236,356	48.8%	\$10,092,314	\$8,430,219	\$5,407,519	\$26,944,557
20031	\$19,921,720	\$16,666,387	\$10,549,307	\$53,178,204	48.4%	\$9,635,879	\$8,061,316	\$5,102,564	\$25,721,611
20032	\$24,058,268	\$20,434,362	\$12,541,568	\$61,013,520	46.4%	\$11,171,572	\$9,488,793	\$5,823,737	\$28,331,919
20033	\$25,535,792	\$21,433,326	\$13,298,797	\$61,989,604	50.4%	\$12,859,435	\$10,793,496	\$6,697,071	\$31,217,018
20034	\$27,082,120	\$22,766,732	\$14,050,910	\$64,769,928	59.0%	\$15,969,369	\$13,424,737	\$8,285,325	\$38,192,536
Total	\$292,148,972	\$261,595,638	\$160,589,870	\$795,274,913	-	\$157,767,041	\$141,617,792	\$86,309,695	\$430,581,952

The value for Other SDUD Utilization in 20004 has been linearly interpolated due to I kely error in SDUD data.

<b>Dey Total</b>	<b>\$816,276,480</b>
<b>Total Difference</b>	<b>\$1,509,609,393</b>

Table B: Dey Albuterol: DIFFERENCE by DMERC and YrQuart

YrQuart	Total Difference					Dey Share of Difference			
	AdminaStar	CIGNA	DMERC-A	Palmetto	Dey Mkt Share	AdminaStar	CIGNA	DMERC-A	Palmetto
19941	\$0	\$12,875	\$0	\$0	29.8%	\$0	\$3,830	\$0	\$0
19942	\$0	\$16,982	\$0	\$0	28.9%	\$0	\$4,906	\$0	\$0
19943	\$0	\$2,414,177	\$0	\$0	27.5%	\$0	\$664,680	\$0	\$0
19944	\$0	\$3,389,074	\$0	\$0	27.3%	\$0	\$924,620	\$0	\$0
19951	\$0	\$3,104,839	\$0	\$0	31.8%	\$0	\$985,905	\$0	\$0
19952	\$0	\$3,983,998	\$0	\$0	34.4%	\$0	\$1,372,374	\$0	\$0
19953	\$0	\$4,183,730	\$0	\$0	34.8%	\$0	\$1,453,876	\$0	\$0
19954	\$0	\$4,139,075	\$0	\$0	32.7%	\$0	\$1,352,907	\$0	\$0
19961	\$0	\$3,615,279	\$0	\$11,522,776	33.0%	\$0	\$1,193,608	\$0	\$3,804,320
19962	\$4,198,004	\$3,371,962	\$0	\$13,143,492	32.9%	\$1,383,109	\$1,110,954	\$0	\$4,330,364
19963	\$0	\$4,197,129	\$0	\$13,094,093	33.7%	\$0	\$1,413,881	\$0	\$4,410,990
19964	\$0	\$4,349,810	\$0	\$13,473,855	31.8%	\$0	\$1,381,186	\$0	\$4,278,325
19971	\$130,054	\$3,843,903	\$0	\$0	32.7%	\$42,496	\$1,256,027	\$0	\$0
19972	\$5,009,598	\$4,615,202	\$0	\$0	34.6%	\$1,731,198	\$1,594,904	\$0	\$0
19973	\$5,243,633	\$4,791,810	\$0	\$16,240,102	35.7%	\$1,870,618	\$1,709,434	\$0	\$5,793,509
19974	\$5,139,692	\$4,909,080	\$0	\$17,181,780	29.9%	\$1,535,283	\$1,466,397	\$0	\$5,132,390
19981	\$257,083	\$322,856	\$0	\$15,131,737	29.9%	\$76,802	\$96,451	\$0	\$4,520,523
19982	\$306,803	\$424,934	\$0	\$17,530,796	29.6%	\$90,848	\$125,827	\$0	\$5,191,055
19983	\$5,304,315	\$4,825,388	\$0	\$17,446,674	30.0%	\$1,592,399	\$1,448,621	\$0	\$5,237,635
19984	\$5,401,680	\$4,828,914	\$0	\$17,312,740	28.8%	\$1,554,560	\$1,389,722	\$0	\$4,982,467
19991	\$4,920,325	\$4,307,152	\$0	\$16,111,224	29.9%	\$1,471,133	\$1,287,800	\$0	\$4,817,113
19992	\$5,405,359	\$4,139,327	\$0	\$18,102,384	32.7%	\$1,765,401	\$1,351,913	\$0	\$5,912,276
19993	\$5,446,801	\$4,240,884	\$0	\$18,605,268	32.4%	\$1,767,123	\$1,375,884	\$0	\$6,036,168
19994	\$6,435,491	\$5,242,907	\$3,412,171	\$21,204,630	29.8%	\$1,914,884	\$1,560,030	\$1,015,293	\$6,309,449
20001	\$6,087,660	\$4,834,484	\$3,339,858	\$20,090,236	28.0%	\$1,703,800	\$1,353,064	\$934,752	\$5,622,808
20002	\$7,757,441	\$5,806,813	\$3,991,087	\$24,823,684	28.9%	\$2,243,582	\$1,679,427	\$1,154,289	\$7,179,425
20003	\$8,256,462	\$5,941,685	\$4,417,581	\$25,316,246	27.5%	\$2,271,711	\$1,634,815	\$1,215,468	\$6,965,597
20004	\$9,160,792	\$6,232,662	\$4,604,996	\$26,567,436	25.1%	\$2,303,354	\$1,567,117	\$1,157,862	\$6,680,014
20011	\$8,796,888	\$5,834,678	\$4,459,817	\$25,370,818	24.2%	\$2,128,154	\$1,411,532	\$1,078,924	\$6,137,739
20012	\$10,909,808	\$7,183,612	\$5,426,955	\$29,395,284	25.2%	\$2,747,508	\$1,809,109	\$1,366,715	\$7,402,860
20013	\$10,828,445	\$7,229,169	\$5,493,715	\$3,266,993	25.6%	\$2,775,369	\$1,852,861	\$1,408,059	\$837,342
20014	\$10,808,172	\$7,823,233	\$5,617,325	\$3,527,117	21.7%	\$2,341,882	\$1,695,114	\$1,217,145	\$764,245
20021	\$10,381,844	\$7,276,686	\$5,301,679	\$29,919,958	11.5%	\$1,195,904	\$838,215	\$610,710	\$3,446,535
20022	\$11,941,738	\$8,390,299	\$6,240,207	\$35,901,092	25.1%	\$2,999,183	\$2,107,235	\$1,567,236	\$9,016,606
20023	\$12,077,517	\$8,453,132	\$6,355,868	\$36,620,524	21.0%	\$2,534,594	\$1,773,979	\$1,333,846	\$7,685,203
20024	\$12,785,782	\$8,667,881	\$6,674,757	\$38,295,640	6.8%	\$868,951	\$589,089	\$453,632	\$2,602,661
20031	\$11,378,033	\$7,651,547	\$5,931,922	\$0	18.9%	\$2,155,164	\$1,449,314	\$1,123,592	\$0
20032	\$14,987,028	\$9,806,930	\$7,347,829	\$0	7.4%	\$1,114,698	\$729,415	\$546,513	\$0
20033	\$15,661,144	\$9,972,525	\$7,644,655	\$0	2.6%	\$406,527	\$258,864	\$198,438	\$0
20034	\$16,534,270	\$10,611,251	\$8,114,018	\$0	7.6%	\$1,263,081	\$810,611	\$619,843	\$0
Total	\$231,551,857	\$204,987,867	\$94,374,436	\$525,196,579	-	\$47,849,317	\$48,085,501	\$17,002,318	\$135,097,618
Dey Total						\$248,034,753			
Total Difference						\$1,056,110,739			



**Table 35rev: Summary of Medicare DME Ipratropium Bromide Results***A. Roxanne Only - With Novaplus*

	Difference	Medicare Paid	Clms w/Diff>0	Total Claims	Prov Payments
Palmetto	\$609,636,482	\$1,075,878,401	6,083,763	6,590,245	586,521
AdminaStar	\$261,316,131	\$391,394,534	2,503,143	2,536,711	260,044
CIGNA	\$207,072,869	\$357,608,096	2,252,198	2,347,762	214,466
DMERC-A	\$91,421,554	\$214,339,752	1,335,160	1,361,541	137,793
Total	\$1,169,447,036	\$2,039,220,783	12,174,264	12,836,259	1,198,824
Percentage	57.35%		94.84%		

*B. Roxanne Only - No Novaplus*

	Difference	Medicare Paid	Clms w/Diff>0	Total Claims	Prov Payments
Palmetto	\$132,307,976	\$1,075,878,401	2,956,249	6,590,245	324,356
AdminaStar	\$29,097,631	\$391,394,534	571,389	2,536,711	86,598
CIGNA	\$42,956,873	\$357,608,096	981,300	2,347,762	106,196
DMERC-A	\$29,937,624	\$214,339,752	570,656	1,361,541	68,906
Total	\$234,300,104	\$2,039,220,783	5,079,594	12,836,259	586,056
Percentage	11.49%		39.57%		

*C. Dey Only*

	Difference	Medicare Paid	Clms w/Diff>0	Total Claims	Prov Payments
Palmetto	\$128,832,369	\$1,075,878,401	2,891,224	6,590,245	305,852
AdminaStar	\$19,567,739	\$391,394,534	472,716	2,536,711	70,405
CIGNA	\$35,043,368	\$357,608,096	974,779	2,347,762	104,070
DMERC-A	\$29,913,421	\$214,339,752	570,672	1,361,541	68,909
Total	\$213,356,897	\$2,039,220,783	4,909,391	12,836,259	549,236
Percentage	10.46%		38.25%		

*D. Dey and Roxanne - With Novaplus*

	Difference	Medicare Paid	Clms w/Diff>0	Total Claims	Prov Payments
Palmetto	\$741,161,688	\$1,075,878,401	6,530,490	6,590,245	616,826
AdminaStar	\$279,827,789	\$391,394,534	2,510,238	2,536,711	262,403
CIGNA	\$246,526,381	\$357,608,096	2,273,300	2,347,762	221,853
DMERC-A	\$148,887,315	\$214,339,752	1,344,218	1,361,541	140,834
Total	\$1,416,403,173	\$2,039,220,783	12,658,246	12,836,259	1,241,916
Percentage	69.46%		98.61%		

*E. Dey and Roxanne - No Novaplus*

	Difference	Medicare Paid	Clms w/Diff>0	Total Claims	Prov Payments
Palmetto	\$584,002,597	\$1,075,878,401	6,516,669	6,590,245	611,835
AdminaStar	\$190,140,045	\$391,394,534	2,298,945	2,536,711	242,015
CIGNA	\$200,039,184	\$357,608,096	2,263,029	2,347,762	218,254
DMERC-A	\$119,500,669	\$214,339,752	1,341,333	1,361,541	139,606
Total	\$1,093,682,495	\$2,039,220,783	12,419,976	12,836,259	1,211,710
Percentage	53.63%		96.76%		

**Table 38B-rev: Dey/Roxane Combined, No NovaPlus: Diffs by DMERC and YrQuart**

YrQuart	Total Difference					Roxane Share of Difference			
	AdminaStar	CIGNA	DMERC-A	Palmetto	Rox rel share	AdminaStar	CIGNA	DMERC-A	Palmetto
19951	\$79,108	\$0	\$0	\$0	0.0%	\$0	\$0	\$0	\$0
19961	\$0	\$0	\$0	\$124	0.0%	\$0	\$0	\$0	\$0
19962	\$0	\$0	\$0	\$1,045	100.0%	\$0	\$0	\$0	\$1,045
19963	\$0	\$0	\$0	\$41	100.0%	\$0	\$0	\$0	\$41
19964	\$0	\$0	\$0	\$1,402,037	100.0%	\$0	\$0	\$0	\$1,402,037
19971	\$0	\$0	\$0	\$1,858,709	98.0%	\$0	\$0	\$0	\$1,822,193
19972	\$1,898,496	\$1,903,721	\$1,133,594	\$0	80.7%	\$1,532,981	\$1,537,200	\$915,345	\$0
19973	\$2,315,717	\$2,316,293	\$1,209,763	\$5,854,096	72.6%	\$1,681,042	\$1,681,460	\$878,199	\$4,249,647
19974	\$2,490,804	\$2,650,759	\$1,332,916	\$6,640,712	64.2%	\$1,598,856	\$1,701,531	\$855,603	\$4,262,696
19981	\$174,611	\$408,424	\$1,421,551	\$7,645,394	58.8%	\$102,729	\$240,289	\$836,345	\$4,498,037
19982	\$282,080	\$709,642	\$1,649,817	\$9,042,595	53.8%	\$151,694	\$381,623	\$887,220	\$4,862,828
19983	\$3,398,839	\$3,526,310	\$1,806,756	\$10,140,264	51.4%	\$1,748,130	\$1,813,692	\$929,272	\$5,215,457
19984	\$3,841,420	\$3,987,694	\$2,055,521	\$11,112,622	46.8%	\$1,797,039	\$1,865,467	\$961,585	\$5,198,551
19991	\$4,056,716	\$4,120,050	\$2,232,750	\$11,846,519	43.0%	\$1,745,209	\$1,772,456	\$960,535	\$5,096,402
19992	\$4,510,971	\$4,255,213	\$2,323,837	\$12,391,550	38.1%	\$1,718,303	\$1,620,881	\$885,188	\$4,720,147
19993	\$5,219,941	\$4,669,854	\$2,478,162	\$15,489,749	34.9%	\$1,822,345	\$1,630,303	\$865,157	\$5,407,661
19994	\$5,534,031	\$6,205,072	\$3,195,133	\$18,372,164	31.5%	\$1,740,945	\$1,952,047	\$1,005,153	\$5,779,680
20001	\$5,783,608	\$6,445,448	\$3,574,239	\$19,855,934	29.4%	\$1,697,914	\$1,892,213	\$1,049,302	\$5,829,177
20002	\$7,995,928	\$7,803,993	\$4,497,863	\$21,256,858	28.0%	\$2,239,081	\$2,185,334	\$1,259,526	\$5,952,508
20003	\$6,707,183	\$8,449,123	\$4,935,459	\$23,322,684	28.2%	\$1,892,926	\$2,384,544	\$1,392,904	\$6,582,216
20004	\$7,270,027	\$9,527,198	\$5,288,193	\$27,135,822	28.9%	\$2,097,554	\$2,748,795	\$1,525,754	\$7,829,250
20011	\$7,519,841	\$8,637,414	\$5,901,864	\$28,493,044	27.1%	\$2,039,063	\$2,342,102	\$1,600,336	\$7,726,110
20012	\$8,743,262	\$10,348,779	\$6,274,919	\$31,589,730	27.0%	\$2,364,810	\$2,799,058	\$1,697,192	\$8,544,146
20013	\$9,235,948	\$10,815,116	\$6,704,073	\$33,645,772	26.0%	\$2,400,121	\$2,810,495	\$1,742,169	\$8,743,435
20014	\$9,880,166	\$10,310,303	\$5,544,012	\$32,228,860	23.6%	\$2,333,522	\$2,435,113	\$1,309,399	\$7,611,893
20021	\$9,568,797	\$10,284,037	\$5,498,875	\$32,596,950	23.6%	\$2,257,939	\$2,426,713	\$1,297,564	\$7,691,867
20022	\$11,195,608	\$11,665,945	\$6,421,182	\$36,110,944	22.1%	\$2,474,276	\$2,578,223	\$1,419,108	\$7,980,670
20023	\$13,847,179	\$12,217,928	\$6,695,414	\$37,821,656	23.5%	\$3,253,674	\$2,870,849	\$1,573,223	\$8,886,962
20024	\$14,670,840	\$12,782,199	\$7,132,497	\$40,216,628	24.4%	\$3,585,851	\$3,124,229	\$1,743,327	\$9,829,761
20031	\$13,725,362	\$11,913,023	\$6,561,198	\$38,145,224	24.4%	\$3,351,582	\$2,909,029	\$1,602,172	\$9,314,644
20032	\$15,942,774	\$10,832,216	\$7,505,046	\$16,137,305	23.7%	\$3,775,570	\$2,565,287	\$1,777,346	\$3,821,639
20033	\$48	\$11,262,167	\$7,837,128	\$19,396,134	20.7%	\$10	\$2,332,841	\$1,623,379	\$4,017,707
20034	\$14,250,744	\$11,991,266	\$8,288,913	\$34,251,432	14.2%	\$2,025,805	\$1,704,610	\$1,178,305	\$4,868,988
Total	\$190,140,046	\$200,039,185	\$119,500,669	\$584,002,598	-	\$53,428,974	\$56,306,384	\$33,770,607	\$167,747,396
Roxane Total						\$311,253,362			
Dey Total						\$782,349,904			
Total Difference						\$1,093,682,499			

## **Attachment B**

January 19, 2010

Renée Brooker  
Assistant Director  
U.S. Department of Justice  
Civil Division-Fraud Section  
610 D Street, NW  
Suite 9918  
Washington, DC 20530

Re: United States of America ex rel. Ven-a-Care of the Florida Keys, Inc. v. Dey, Inc., et al.,  
MDL 1456

Dear Ms. Brooker,

This letter provides a brief supplement to my earlier discussions and specifically addresses certain arguments made by Dr. David Bradford.

A. Dr. Bradford's "Dispensing Fee Shortfall"

1. In his report, Dr. Bradford argues, in essence, that state Medicaid agencies purposefully paid inflated ingredient costs to "cross-subsidize" inadequate dispensing fees, and that more than half of my "difference" calculation is attributable to this cross-subsidization. On page 60 of his report, Dr. Bradford attempts to quantify a "dispensing fee shortfall," and in Figure 41 (on page 134) and in even-numbered figures from 128 through 144 of Appendix G, he reduces my damages calculations for 14 states by the amount of this "dispensing fee shortfall," among other adjustments.<sup>1</sup> His discussion in paragraphs 126 and 135 (on pages 54-55 and 60, respectively) implies (but does not state) that his shortfall calculation is based on data from a 2007 unpublished study by Grant Thornton which estimates average pharmacy dispensing costs in 2006. Later, in footnote 294 (on page 130), Dr. Bradford explains that he "extrapolates" from the 2006 Grant Thornton cost estimates to earlier years using medical consumer price index data. I note that in Appendix G there is no explanation of how the "dispensing fee shortfalls" shown in that Appendix were calculated.

2. In my Rebuttal Report dated April 23, 2009, I explain why it is inappropriate to speculate about what states might have done had Dey and other manufacturers reported truthful pricing information. I believe my reasoning is correct. There is another reason, however, why Dr. Bradford's calculation of "dispensing fee shortfalls" is improper.

3. I have reviewed the electronic files produced by Dr. Bradford and used to generate his "dispensing fee shortfall" calculations, located in sub-folders of the folder named "Medicaid dispensing fee shortfall." The sub-folder named "Scripts" contains a Stata script named "01 Dispensing fee shortfall MA.do" which correctly calculates "dispensing fee shortfalls" for

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<sup>1</sup> Dr. Bradford applies a similar quantification of "dispensing fee shortfall" to an additional 17 states in Figure 43 and 18 (with the addition of Maine) in the odd-numbered figures from 129 through 145 of Appendix G.

Massachusetts under Dr. Bradford's assumptions and saves these calculations in the Stata data file named "Individual dispensing fee shortfall calculations MA.dta" in the sub-folder named "Output."<sup>2</sup>

4. In another Stata script named "create differences summary.do," produced in association with Bradford's Figure 41, the Massachusetts-only quarterly "dispensing fee shortfalls" contained in the Stata data file named "Individual dispensing fee shortfall calculations MA.dta" are applied to all claims in all states. The results of this script match the values listed in Figure 41. Similar Stata scripts apply the same Massachusetts-only quarterly "dispensing fee shortfalls" to all states in Figure 43 and in figures 128 through 145 of Appendix G. It is apparent from the Stata files described above that Dr. Bradford has calculated his "dispensing fee shortfall" by extrapolating from a sample of one state (Massachusetts) to 31 other states in Figures 41, 43 and Figures 128 through 145 of Appendix G.

5. Although in appropriate circumstances extrapolation is an acceptable methodology, in this situation it is not. Dr. Bradford's extrapolation is inappropriate in that it makes two factual errors. First, it assumes that all states historically paid the same dispensing fees as Massachusetts. Second, it assumes that all states should have paid the same dispensing fees Massachusetts should have paid, as estimated by Grant Thornton. These assumptions are inconsistent with both the Myers and Stauffer methodologies as well as the Grant Thornton documents cited by Dr. Bradford. Additionally, Dr. Bradford applies the Massachusetts-only "dispensing fee shortfall" to every claim in all states, regardless of whether the payment for the original claim included a dispensing fee amount.

6. According to Dr. Bradford's own analysis, Massachusetts in 2006 is clearly not representative of all other states for all years (1991 - 2006) with respect to the difference between the dispensing fee and dispensing costs. This is demonstrated in Figure 15 of Dr. Bradford's report (on page 55), where he states that Massachusetts paid a dispensing fee that was only 33% of the dispensing costs estimated by Grant Thornton, whereas all but seven other states had more generous dispensing fees and correspondingly lower shortfalls.

#### B. Dr. Bradford's Opinions Regarding Medicare Payment

1. My earlier reports address the shortcomings in Dr. Bradford's discussion of Medicare. It is appropriate to further point out that his discussion relating to the Medicare Prescription Drug, Improvement and Modernization Act of 2003, Pub. L. 108-173 (MMA) and the subsequent establishment of dispensing fees for inhalation therapy drugs is misleading. In describing the supposed Medicare cross-subsidy (on pages 117 and 118 and in Figure 33 of his report), Dr. Bradford claims to illustrate Medicare payments for cromolyn sodium. (The relevance of this is unclear, since I did not calculate Medicare damages for this drug.) In paragraph 257 on page 120, Dr. Bradford compares Medicare reimbursement for this drug, in

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<sup>2</sup> A Stata script contains instructions that can be performed by Stata, a commercially available statistical analysis software program. A Stata data file contains data in the form of records and fields in a format suitable for use by Stata.



2004 versus 2005, to imply that after the MMA, Medicare intended to pay even more than it had paid before. It is clear, however, that neither 2004 nor 2005 is useful to such an analysis. The year 2004, shown in the left-hand bar of Figure 33, is not representative of pre-MMA Medicare reimbursement because the MMA became effective January 1, 2004, and, by law, reimbursement for inhalation therapy drugs for that year was pegged at 80 percent of AWP, for one year only, as an interim transition to the “average sales price”-based reimbursement that took effect January 1, 2005.<sup>3</sup> Before the MMA, Medicare paid at 95 percent of AWP, not 80 percent of AWP.<sup>4</sup> If one were to show Medicare payments before the MMA, when reimbursement was at 95 percent of AWP, the bar would be considerably higher.

2. Dr. Bradford’s illustration of post-MMA payments in 2005, with a high dispensing fee, is similarly misleading because that year was also a transition year. CMS established an interim dispensing fee of \$57 for inhalation therapy drugs for 2005 only, based on a report prepared for and submitted by pharmacy lobbying organizations.<sup>5</sup> Later CMS concluded that this fee was excessive and reduced it to \$57 for only the first 30-day supply,<sup>6</sup> and \$33 for subsequent 60-day supplies and \$66 for 90-day supplies (resulting in an overall average of about \$35). A bar graph showing reimbursement in 2006 would show the typical 30-day payment to be considerably lower.

3. Bradford repeats these mistakes when he attempts to show Medicare payments for compounded solutions of albuterol and ipratropium bromide (on pages 118-119 and in Figure 34). His Figure 34 purports to compare 2004 payments for a typical 30-day supply of the pharmacy-compounded solution of albuterol sulfate and ipratropium bromide with payments in 2005. The bar for 2005 is based on payment under a new HCPCS code, J7616, which was introduced effective January 1, 2005. Dr. Bradford’s chart suggests that the government decided to increase reimbursement for the same pharmacy-compounded formulations. However, the HCPCS code J7616 (which was eliminated effective January 1, 2006<sup>7</sup>) had no application to pharmacy-compounded albuterol and ipratropium bromide drugs at issue in this case. As DMERC Medicare Advisories clearly advised, “Code J7616 . . . may only be used when these drugs are provided in combination by a manufacturer or repackager in a vial with a single NDC number. DuoNeb is one example of J7616. Despite the narrative description of the code, J7616 and J7617 must not be used for inhalation solutions of these drugs that are compounded by pharmacies.”<sup>8</sup> In short, J7616 was applicable to DuoNeb, which, while it is a Dey product, it is

<sup>3</sup> Pub. L. 108-173 (§ 305(a)), 117 Stat 2066, 2238-2239, codified at 42 U.S.C. § 1395u(o)(1)(G).

<sup>4</sup> Balanced Budget Act of 1997 (BBA), Pub. L. 105-33, 111 Stat. 462-463 (1997) (effective January 1, 1998). Before that, Medicare paid at 100 percent of AWP. 56 Fed. Reg. 59502, 59621 (Nov. 25, 1991).

<sup>5</sup> 69 Fed. Reg. 47488, 47546-47550 (Aug. 5, 2004) (proposed rule); 69 Fed. Reg. 66236, 66425 (Nov. 15, 2004) (final rule).

<sup>6</sup> This has been described by a DME Medicare Administrative Contractor as a “once in a lifetime fee [which] only applies to beneficiaries who are using inhalation drugs for the first time as a Medicare beneficiary on or after 01/01/2006.”

<sup>7</sup> See Region C DMERC Medicare Advisory, Spring 2006, at pp. 28-29. Code J7616 was replaced by J7620 which similarly applied to DuoNeb.

<sup>8</sup> LCD for Nebulizers (L11499), Region A (2005); Region A DMERC PSC Bulletin December 2004; Spring 2005 Region C DMERC DMEPOS Supplier Manual (pp. 21.3 - 21.4).

not one of the drugs alleged in the government's complaint. The 2005 Medicare payment for DuoNeb, which is compounded by Dey in the manufacturing process, is not in any way comparable to payment for pharmacy-compounded albuterol and ipratropium bromide. Dr. Bradford's comparison of payment for these very different drug formulations (pharmacy-compounded formulations versus DuoNeb) is unhelpful and misleading.

### C. "Accounting Losses" to Pharmacies

1. Dr. Bradford criticizes me for not considering a "but for" world in which marginal pharmacies would lose money if they were reimbursed at the levels suggested by my alternative AWP (in paragraph 13 on page 7 of his Rebuttal Report). Dr. Bradford calculates "accounting losses" that he argues "marginal pharmacies" would experience if my alternative AWP were used as the basis for reimbursement for the subject Dey drugs (see paragraph 287 and Figure 39 on pages 130-131).

2. Dr. Bradford's "accounting losses" argument is inconsistent with the arguments appearing elsewhere in his report and rebuttal, that it is necessary to consider what would happen if all manufacturers reports truthful AWP. He calculates "accounting losses" for only the Dey drugs that are the subject of the government's complaint (on pages 130-131), without regard to pharmacy income from other drugs. Yet, as he alludes to elsewhere, the subject Dey drugs are inexpensive, especially compared to brand drugs, and therefore a spread between AAC and AWP generates smaller dollar margins, whereas the spread on an expensive brand drug generates a much larger dollar margin (on pages 14-15). The great majority of states use the same reimbursement methodology for both brand and generic drugs. As I observed in my Rebuttal Report, brand drugs account for a large majority of Medicaid prescription drug spending, and if one were to scale actual average prices by 1.25 for all pharmaceutical products' AWP, it is plausible that pharmacies would on average have higher ingredient cost reimbursement overall. It is virtually certain that marginal pharmacies would not experience the "accounting losses" described by Dr. Bradford.

### D. Dey and Roxane, Ipratropium Bromide

1. In the discussion of my January 23, 2009, report concerning Medicare and ipratropium bromide, I explained how replacing the Dey and Roxane products' AWP in an array will cause the median to fall substantially more than occurs if one replaces only the Dey AWP (see e.g., pages 113 and 128). I explained that the combined DIFFERENCE more accurately captures the loss to the Medicare program resulting from inflated AWP of both Dey and Roxane. To further illustrate why it is appropriate to consider the impacts of both companies' AWP in combination, it is useful to consider the CIGNA arrays for 2001 Q3 and 2001 Q4 (setting aside for the moment the effect of Roxane's NovaPlus products) (Copies of these arrays are attached). In the 2001 Q3 array, reducing Dey's AWP by even a few cents changes the median. The same is true with respect to the Roxane AWP. Changing the AWP of both companies' products changes the median even more.

2. In the 2001 Q4 array, however, the situation is markedly different. This array is the same as the 2001 Q3 array, with the notable exception being that one new product, manufactured by Apotex Corp., is included in the array. Thus, in contrast to the 2001 Q3 array, due to the addition of the Apotex AWP, in the 2001 Q4 array the median is not affected by changing the AWP of any single manufacturer. Instead, given the nature of the median statistic, the value of the Apotex AWP and the number and values of other AWPs in the array, the median is changed only by changing the AWPs of two or more manufacturers.

3. If one replaces the AWPs of both Dey's products and Roxane's generic products, the median is reduced considerably, which clearly demonstrates that Medicare would have paid less if both Dey and Roxane had reported lower AWPs. If one were to consider only the impacts of the Dey and Roxane AWPs in isolation from one another, the loss to the Medicare program would not be captured. It would not be logical to conclude that, due to the addition of just one new (and possibly inflated) AWP to the array, the United States is unable to recover for losses that have plainly been proven.

In addition to the above, my report in this case should be considered supplemented by my letter to you dated November 30, 2009 (including the supplements referenced in that letter), as well as my Declarations dated July 23, 2009, and September 21, 2009 and my deposition testimony given in this case. Also, I reserve the right to update or supplement my analysis if additional information becomes available, and to prepare additional summaries, graphical materials, or charts to use at trial.

Sincerely,

A handwritten signature in cursive script, appearing to read "Mark G. Duggan".

Mark G. Duggan, Ph.D.



ORIGINAL ARRAY (Per Carrier Array Documents)

DMERC Medication Pricing

CODE	DESCRIPTION	UNIT DOSAGE	PRICE LIST DRUG NAME	LISTED PACKAGING	NDC NUMBER	AWP FROM RED BOOK	RED BOOK DATE	PAGE NUMBER	UNITS PER PACKAGING	COST/UNIT DOSAGE	DATE LAST UPDATED	UPDATED BY
J7644	Ipratropium Bromide	1 mg	Dey	.02%, 2.5ml 25s	49502-0685-03	\$ 44.10	Apr-01	CD	12.5	\$ 3.53	6/15/2001	CH
	Unit dose		Dey	.02%, 2.5ml 30s	49502-0685-33	\$ 52.80	Apr-01	CD	15	\$ 3.52	6/15/2001	CH
			Dey	.02%, 2.5ml 60s	49502-0685-60	\$ 105.60	Apr-01	CD	30	\$ 3.52	6/15/2001	CH
			Roxane	.02%, 2.5ml 25s	00054-8402-11	\$ 44.06	Apr-01	CD	12.5	\$ 3.52	6/15/2001	CH
			Roxane	.02%, 2.5ml 30s	00054-8402-13	\$ 52.87	Apr-01	CD	15	\$ 3.52	6/15/2001	CH
			Roxane	.02%, 2.5ml 60s	00054-8402-21	\$ 105.74	Apr-01	CD	30	\$ 3.52	6/15/2001	CH
			Alpharma USPD	.02%, 2.5ml 25s	00472-0751-23	\$ 56.50	Apr-01	CD	12.5	\$ 4.52	6/15/2001	CH
			Alpharma USPD	.02%, 2.5ml 30s	00472-0751-30	\$ 67.80	Apr-01	CD	15	\$ 4.52	6/15/2001	CH
			Alpharma USPD	.02%, 2.5ml 60s	00472-0751-60	\$ 118.80	Apr-01	CD	30	\$ 3.96	6/15/2001	CH
			Phys Total Care	.02%, 2.5ml 25s	54868-4082-01	\$ 23.54	Apr-01	CD	12.5	\$ 1.88	6/15/2001	CH
			Phys Total Care	.02%, 2.5ml 60s	54868-4082-00	\$ 42.25	Apr-01	CD	30	\$ 1.41	6/15/2001	CH
			Allscripts	.02%, 2.5ml 25s	54569-4910-00	\$ 18.62	Apr-01	CD	12.5	\$ 1.49	6/15/2001	CH
	Generic Median =	\$ 3.52										
			Atrovent									
			(Boehr Ingelheim)	.02%, 2.5ml 25s	00597-0080-62	\$ 68.90	Jun-01	20	12.5	\$ 5.51	6/15/2001	CH
			Ipratropium Bromide NovaPlus									
			(Roxane)	.02%, 2.5ml 25s	00054-8404-11	\$ 44.06	Apr-01	CD	12.5	\$ 3.52	6/15/2001	CH
			(Roxane)	.02%, 2.5ml 30s	00054-8404-13	\$ 52.87	Apr-01	CD	15	\$ 3.52	6/15/2001	CH
			(Roxane)	.02%, 2.5ml 60s	00054-8404-21	\$ 105.74	Apr-01	CD	30	\$ 3.52	6/15/2001	CH
	Lowest Brand =	\$ 3.52										
	Allowable =	\$ 3.52	Updated through June 2001 Red Book updates									
	Allowable less 5% =	\$ 3.34										

KO & KP	\$	3.52
UD(gm) x		0.5
=		1.76
J7051 -		0.22
=		1.54
UD(gm) -		0.5
KQ	\$	3.08

J7644KQ LESS 5% = \$ 2.93

Computed(Atrovent) product removed from array per October 1999 CD item deactivated 6/8/99

ORIGINAL ARRAY (Per Carrier Array Documents)

## DMERC Medication Pricing

[illegible]

KO & KP	\$	3.52
UD(gm) x		0.5
=		1.76
J7051 -		0.22
=		1.54
UD(gm) -		0.5
KQ	\$	3.08

J7644KQ LESS 5% = \$ 2.93

Compumed(ATrovent) product removed from array per October 1999 CD item deactivated 6/8/99

## **Attachments C through E are omitted**

They may be found with the declaration originally filed as  
Exhibit 4 to the Memorandum of United States in Support  
of Motion to Exclude Certain Testimony of W. David Bradford, Ph.D  
(Master Doc. #6914-9, Subcategory #693-9)